

65. (New) The apparatus of claim 58, further comprising z-direction positioning means for the reciprocal punch.

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66. (New) The apparatus of claim 59, further comprising z-direction positioning means for the reciprocal punch.

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### REMARKS

The Official Action mailed December 19, 2001 has been reviewed and the comments of the PTO carefully considered. Claims 27, 29, 30 and 36 have been amended for clarification purposes. Claims 51-66 have been added. Support for the new claims is found in the specification as follows: claim 51 at page 6, line 32 – page 15, line 33; claim 52 at page 14, lines 19-28; claim 53 at page 13, lines 23-28 and FIG. 13; claim 54 at page 18, lines 4-6; claims 55 and 56 at page 6, line 32 – page 7, line 11; claim 57 at page 7, lines 14-19; claim 58 at page 13, line 22 – page 14, line 1 and FIGS. 13 and 14; claims 59-61 at page 13, line 22 – page 15, line 33 and FIGS. 13 and 14; claims 62 and 63 at page 15, lines 20-21; and claims 64-66 at page 14, lines 18-24 and page 15, lines 8-14. Entry of these amendments is respectfully requested. Claims 1-66 are pending.

#### Restriction Requirement under 35 U.S.C. §121 and §372

Applicants hereby affirm the election of claims 26-37 (group II) in response to the restriction requirement. The restriction requirement between groups II (claims 26-37), III (claims 38-45), and IV (claims 46-50) is respectfully traversed. The Office Action indicates that “the technical feature linking the inventions of Groups I-IV appears to be the array for performing an analysis of biological specimens comprising: donor specimens in a receptacle at fixed assigned locations which locations are maintained and recorded.” The PTO’s position is that unity of invention is lacking since the linking technical feature allegedly is taught by Battifora et al. Applicants further note that the claims of groups II, III and IV include an additional corresponding technical feature since they all relate to apparatuses or devices for

making the array that includes a punch for delivering tissue donor specimens into the fixed assigned locations of the array.

Battifora et al. discloses a process for preparing multi-specimen slides useful in immunohistologic analyses. It is clear that Battifora et al. does not teach preparing arrays that includes placing donor specimens in fixed assigned locations that are maintained as recited in claim 1. According to column 2, line 54 to column 3, line 23 of Battifora et al., tissue specimen strips 16 are first placed in a mold 18. An embedding medium then is introduced into the mold 18 to produce a solidified embedding structure 19 that includes the tissue specimen strips 16. A plurality of the embedding structures 19 are subsequently stacked into a multispecimen block and then sectioned to prepare the multi-specimen slides. In contrast to the method presently recited in claim 1, the tissue specimen strips 16 are not fixed and maintained in a location in the mold 18 receptacles since they are eventually removed from the mold 18 to prepare the solidified embedding structure 19. It is the subsequent embedding step in Battifora et al. that fixes the specimens as opposed to initially fixing the location of the specimens as they are placed in a first recipient member. Thus, the corresponding technical feature identified by the PTO does define a contribution over Battifora et al.

#### Abstract

The Office Action states the application does not contain an abstract. However, an abstract on a separate sheet of paper was filed as part of the PCT application of which this application is a national stage application. A copy of the abstract as filed is appended herewith as Exhibit A.

#### 35 U.S.C. §112, second paragraph rejections

The §112, second paragraph rejections have been obviated by the present amendments to claims 27, 29, 30 and 36. It is respectfully submitted that original claims 27, 29, 30 and 36 were not unclear since the Examiner understood the claim language sufficiently to suggest correct amendments. In any event, the claims were amended to advance prosecution of the application. Applicants do note that the term "corresponding" in claim 29 is clear based on the description in

the specification regarding the relationship between structures of interest and tissue specimen regions in the donor block (see page 7, line 33 – page 8, line 2). Moreover, §112, second paragraph does not prohibit “non-specific relational” terms in the claims.

35 U.S.C. §102 rejections

A. Claims 26-30 and 36 are not anticipated by Barrere et al.

Barrere et al. relates to a device for withdrawing a core sample from a semi-solid material and depositing it on another medium. Column 2, lines 1-22 of Barrere et al. is cited as describing the subject matter of claim 26. Upon close inspection of Barrere et al., it becomes apparent that there is no disclosure of an apparatus that includes two distinct holders as recited in claim 26.

Only one holder is mentioned in column 2, lines 1-22. Further reading of the text at column 2, lines 41-66 and examination of FIG. 1 confirms that the Barrere et al. device includes only one holder – namely, holder 25 that supports punch 26. There is no other structure described or suggested by Barrere et al. that could be considered to be a second holder. The §102 rejection of claims 26 (and claims 27-30 and 36 that depend therefrom) over Barrere et al. should be reconsidered and withdrawn since Barrere et al. does not disclose all the features recited in claim 26.

Applicants further note that the holder 25 of Barrere et al. itself does not include an x-y positioning device as recited in claim 27. The device of Barrere et al. also does not include a stylet (the spigot 31 appears to be simply a void within body 27) as recited in claim 28 since compressed air is used in the Barrere et al. device to expel the specimen from the punch.

B. Claims 26, 28, 30, 34, 36 and 37 are not anticipated by Furmanski et al. (as defined by Webster's Ninth New Collegiate Dictionary)

Furmanski et al. relates to a method for preparing multiple tissue specimens. Various components or tools are used in the method, but contrary to the PTO's assertion, there is no description of a recipient block holder as recited in claim 26. Specifically, the PTO considers

the grooved plate shown in FIG. 1B of Furmanski et al. to constitute a recipient block holder. The PTO also states that the grooves in the grooved plate are an array of receptacles per claim 26. In other words, according to the PTO, Furmanski et al. discloses a recipient block holder (i.e., grooved plate) that includes an array of receptacles (i.e., the grooves). However, according to claim 26, the recipient block, rather than the recipient block holder, includes the array of receptacles. If the grooved plate is the recipient block holder, then Furmanski et al. does not disclose a recipient block that comprises an array of receptacles. Accordingly, the §102 rejection of claim 26 (and claims 28, 30, 34, 36 and 37 that depend therefrom) over Furmanski et al. should be reconsidered and withdrawn.

35 U.S.C. §103 rejections

A. Claims 31-33 are not obvious over Barrere et al. combined with Bernstein et al.

Dependent claim 31 recites an apparatus that includes the features of claim 26 and a recorder for recording coordinate positions of the receptacles in the recipient block. Bernstein et al. is relied upon by the PTO only for teaching a similar apparatus that includes a recorder for recording coordinate positions. Bernstein et al. does not cure the fatal deficiencies in Barrere et al. noted above with respect to claim 26, and for this reason alone dependent claims 31-33 also recite patentable subject matter.

In addition, Bernstein et al. describes a system that includes analysis processing workstations that are disposed in a set of grid locations that may be specified by coordinates. According to column 5, lines 33-34, the Bernstein et al. system can include “a PC type computer which utilizes process control programs and assay development software.” However, there is no mention in the passage of Bernstein et al. cited by the PTO (column 5, lines 30-50) that the PC type computer records the coordinate positions of the analysis processing stations. Moreover, Bernstein et al. is concerned with the position of the individual workstations rather than the coordinates associated with samples that are at a single workstation. It follows that a combination of Barrere et al. and Bernstein et al. would not have resulted in the apparatus recited in claim 31 since Bernstein et al. does not teach a recorder, even assuming *arguendo* that there would have been motivation to make the combination.

In fact, there would have been no motivation to modify a single specimen sampling device (Barrere et al.) by selecting one component from a plurality of components of a multiple workstation system (Bernstein et al.). This lack of motivation is especially evident from Bernstein et al.'s failure to identify the PC type computer as more critical relative to the other components of Bernstein et al.'s system. Furthermore, Bernstein et al. relates to a system for transporting entire samples (e.g., blocks or slides) through various stages such as fixing and embedding. Barrere et al., on the other hand, relates to a single device for preparing a specimen. A skilled artisan would not have been prompted to combine such disparate teachings.

The PTO states that it would have been obvious "to further include a computer implemented recorder to coordinate positions of the receptacles" of Barrere et al. However, the PTO has not pointed to where Barrere et al. discloses an array of receptacles, much less any need to coordinate their positions. For these reasons, the pending §103 rejection of claims 31 (and claims 32 and 33 that depend therefrom) should be reconsidered and withdrawn.

B. Claims 34 and 37 are not obvious over Barrere et al. combined with Furmanski et al.

The first sentence of section 14 of the Office Action indicates that claims 34 and 37 would have been obvious over Bernstein et al. combined with Furmanski et al. The remarks following the first sentence though refer to Barrere et al. rather than Bernstein et al. Applicants assume that the mention of Bernstein et al. in the first sentence was an inadvertent error.

Dependent claim 34 recites an apparatus that includes the features of claim 26 and a sectioning device for sectioning the recipient block. Furmanski et al. is relied upon by the PTO only for teaching a sectioning device. Furmanski et al. does not cure the fatal deficiencies in Barrere et al. noted above with respect to claim 26, and for this reason alone dependent claims 34 and 37 also recite patentable subject matter.

Furthermore, the requisite motivation to combine Barrere et al. with Furmanski et al. is lacking. The specimens obtained by the Barrere et al. device "are forced out onto the upper surface of the agar" (column 4, lines 2-3). There is no suggestion in Barrere et al. that the specimens are inserted into the agar so that the specimens are encompassed by the agar. A skilled artisan would not have been prompted to couple the Barrere et al. device with a sectioning device for sectioning the agar since the resulting sections would not have included any

of the specimen as it remains on the surface of the agar. The PTO states that there would have been motivation to combine these references “for the expected benefit of efficient and rapid analysis sample [sic] at the microscopic level as taught by Furmanski et al.” The efficiency allegedly provided by the Furmanski et al. device derives from its alleged improvement – assembling a plurality of cores in holder – rather than sectioning. Thus, a skilled artisan reading Furmanski et al. would not have been motivated to utilize sectioning to improve the efficiency of another device.

C. Claim 35 is not obvious over Barrere et al. combined with Furmanski et al. and Bernstein et al.

The first sentence of section 15 of the Office Action indicates that claim 35 would have been obvious over Bernstein et al. combined with Furmanski et al. and Bernstein et al. Applicants assume that “Bernstein et al.” was inadvertently substituted for “Barrere et al.” in the first sentence.

Claim 35 recites an apparatus that includes a recorder and the subject matter of claims 26 and 34. The combination of these cited references would not have resulted in the apparatus of claim 35 for the reasons explained above in connection with claims 26 and 34. Specifically, there would be no motivation to combine Furmanski et al. with Barrere et al. and Bernstein et al., in fact, does not teach a recorder. The pending §103 rejection of claim 35 over Barrere et al. combined with Furmanski et al. and Bernstein et al. should be reconsidered and withdrawn.

New independent claims 51, 55, 58 and 59 are patentable over Barrere et al.  
and Furmanski et al.

The apparatus recited in new claim 51 includes means for holding a tissue donor block and means for holding a recipient block. Barrere et al. does not describe or suggest either one of such means and Furmanski does not describe or suggest means for holding a recipient block.

The device recited in new claim 55 includes a punch apparatus that includes a guide surface, and a punch base slidably mounted on the guide surface. Neither Barrere et al. nor Furmanski describe or suggest a punch apparatus that includes these features.

The apparatus recited in claim 58 includes a tissue donor block holder disposed on an x-y positioning platform and a recipient block holder disposed on an x-y positioning platform. Neither Barrere et al. nor Furmanski describe or suggest disposing such types of holders on an x-y positioning platform.

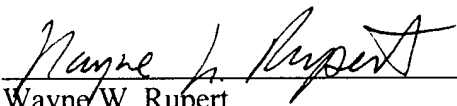
The integrated apparatus recited in claim 59 includes a donor block holder, a reciprocal punch, and a recipient block holder. Neither Barrere et al. nor Furmanski describe or suggest an integrated apparatus that includes these three features.

Conclusion

It is respectfully submitted that the present claims are in condition for allowance. In particular, the §102 and §103 rejections should be withdrawn since neither Barrere et al. nor Furmanski et al. teach the claimed invention. Should there be any questions regarding this application, Examiner Forman is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

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**Marked-up Version of Amended Specification and Claims  
Pursuant to 37 C.F.R. §§ 1.121(b)-(c)**

**In the specification:**

The following paragraph has been added prior to line 3 on page 1:

**PRIORITY CLAIM**

This application was filed as a 35 U.S.C. § 371 application of PCT International Application No. US99/04001 filed February 24, 1999, which designated the United States and was published in English under PCT Article 21(2), and which in turn claims benefit of U.S. Provisional Application 60/075,979, filed February 25, 1998.

**In the claims:**

The claims have been amended as follows:

27. (Amended) The apparatus of claim 26, wherein the recipient block holder comprises an x-y positioning device that can be incrementally moved to align sequential receptacles and the reciprocal punch.

29. (Twice amended) The apparatus of claim 26, further comprising a positioner for positioning [a reference slide] over the donor block a reference slide that includes at least one structure of interest, to align [structures] the at least one structure of interest in the reference slide with corresponding tissue specimen regions in the donor block.

30. (Amended) The apparatus of claim 26, further comprising a [separate] second reciprocal punch capable of being positioned relative to the recipient block for punching the array of receptacles in the recipient block, wherein the [separate] second reciprocal punch is different than the reciprocal punch positioned to punch the specimen from the tissue donor block.



36. (Twice amended) The recipient block of claim 26, wherein the recipient block comprises a regular array of spaced biological specimens in fixed assigned locations.